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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,866	04/11/2005	John-Olov Jansson	JANSSON7	2241

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BROWDY AND NEIMARK, P.L.L.C.
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WASHINGTON, DC 20001-5303

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/530,866

Applicant(s)

JANSSON, JOHN-OLOV

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,14,15,18,20,22,27,28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10,14,15,18,20,22,27,28 and 30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the responses filed 10/23/06 and 1/9/07, no claim has been added, deleted, or amended. Claims 1-10, 14, 15, 18, 20, 22, 27, 28 & 30 remain pending.

Applicants elections (filed 10/23/06 and supplemental filed 1/9/07) are acknowledged.

In response to the restriction requirement, applicants have elected group I (claims 1-10, 14 & 15).

- a) in the elected method, one and only one of G1-G4 is required
- b) the peptide native human ghrelin;
- c) in the elected method, a composition that comprises a peptide is administered (as opposed to a peptide *per se*)
- d) in the elected method, a composition is administered that contains native human ghrelin and water;
- e) the route of administration is subcutaneous (*as per* the response filed 1/9/07)



Applicants have traversed the species election requirement by arguing that the examiner must provide evidence that there is at least one embodiment within the claimed invention that is obvious over (or anticipated by) the prior art. Applicants have not provided an authority for this proposition. However, whether evidence of obviousness must be provided before the election requirement, or after will make no difference on the ultimate outcome of the prosecution. If it is really true that no one (in the prior art) has ever

suggested the administration of a peptide for one of the uses listed in claim 1, such that application of the term “analog” would be defensible, then the election requirement will prove to be moot. Given the broad meaning of the term “ghrelin analog”, novelty of claim 1 in its present form is unlikely to be the ultimate finding. Nevertheless, applicants would be correct in arguing that the examiner does bear the burden, during the course of prosecution to find evidence that analogs have been used in accordance with claim 1.

As for the distinction between claims 1 and 18, applicants have implied that, in the event that the examiner were to find a reference which forms the basis for a valid 103 rejection of claim 1, applicants would have no objection to the examiner also rejecting claim 18, even if the reference(s) in question made no mention of another stomach derived factor. If this represents applicants’ actual views on the matter, then it is a virtual certainty that an accommodation will be reached with regard to the restriction. In any case, if one or more of the Group I claims are found allowable, claims 18 and 20 will likely be rejoined therewith (subject to the same limitations).

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The definitions of G1-G4 are reiterated below:

G1: a method for treating and/or preventing loss of body weight and body fat in a gastrectomized individual;

G2: a method for preventing or treating cachexia in a gastrectomized individual;

G3: a method for stimulating appetite and/or stimulating food intake in a gastrectomized individual;

G4: a method for stimulating weight gain and/or increasing body fat mass in a gastrectomized individual;

Applicants are required under 35 U.S.C. §121 to elect a disclosed subgenus for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Election is required of one of G1, G2, G3 and G4.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. . 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER

